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### **EUROPEAN PATENT APPLICATION**

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- Nutrient composition for athletes and method of making and using the same.
- A unique, chemically-defined nutrient composition is disclosed which can enable stressed, catabolic, marathon athletes to achieve superior performance. The diet provides substantially all of the essential nutrients along with flavoring aids in simple, readily available form and comprises free amino acids, vitamins, minerals and trace elements, electrolytes, simple and complex carbohydrates, and flavoring aids. This diet benefits athletes because it provides for substantially all of the nutritional requirements, allows for reproducibility and user familiarity through precise chemical definition, supplies optimal nutritional requirements during training and competition through unique tailoring to the nutritional requirements of an individual athlete, requires minimal digestive energy, and encourages maximal absorption of nutrients. A specific mixture of amino acids, carbohydrates, and flavoring aids is used to achieve superior taste. In addition, due to the unique method provided in the present invention, all of the solid nutrients rapidly and completely dissolve in tap water under ordinary usage conditions. This enables the fine blend to be easily dissolved in an appropriate volume of tap water prior to use by the athlete.

#### Description

# NUTRIENT COMPOSITION FOR ATHLETES AND METHOD OF MAKING AND USING THE SAME

Background of the Invention

The present invention relates to nutrient compositions for athletes, to be used in connection with training and competition, as well as to the methods for producing and using those compositions. In particular, the invention relates to an orally ingestible palatable blend which provides substantially all of the nutritional, carbohydrate, and energy requirements of an athlete under conditions of physical stress, without interfering with fluid absorption or causing gastrointestinal disturbances. The invention additionally relates to a new method of preparation of solid nutrients which allows for rapid and complete dissolution of the final blend in tap water under ordinary use conditions.

The use of sport drinks to satisfy various requirements of athletes during training and competition is known. Known drinks are used to provide energy and replace lost electrolytes and nutrients. Sport drinks that are currently on the market generally fall into one of four categories. The first category includes sports drinks that contain only sugar and water. The sports drink marketed under the name "Max" by Coca Cola Company is an example. That drink contains a five percent (5%) solution of dextrose and maito-dextrin.

The second category includes sports drinks that consist of sugars, plus some electrolytes, in water.

The third category consists of sport drinks that contain sugars, some electrolytes, and some vitamins. The sports drinks "Gatorade" (marketed by Stokely-Van Camp, Inc.) and "Exceed" (marketed by the Ross division of Abbott Laboratories) are examples. Gatorade contains a six percent (5%) solution of sucrose and glucose, 220 mg of sodium and 50 mg of potassium per serving and some vitamin C. "Exceed" has glucose polymers and fructose, 280 mg of sodium, 430 mg of potassium, 380 mg chloride and other electrolytes in every 8 ounce

The fourth category includes sports drinks consisting of sugars, some electrolytes, some vitamins, and some minerals. The sports drinks "Body Fuel 450" (marketed by Vitex Foods, Inc.). and "Pripps Plus" (marketed by Aktiebolaget Pripps Bryggrier) are examples.

Although not directed to the particular nutritional needs of athletes, U.S. Patent No. 3,697,287 to Winitz discloses what is said to be a palatable food composition which contains all of the essential amino acids, essential minerals, and carbohydrates. The invention disclosed therein claims to achieve palatability by (a) minimizing amino acids or amino acid derivatives which contain sulfhydryl (SH) groups; (b) minimizing amino acids or their derivatives whose taste is incompatible with the flavor of the mixture of the other ingredients; and (c) minimizing the use of amino acids or their derivatives that are not of sufficient purity. Winitz also discloses a pH dependence of the flavor of certain Ingredients. That invention also discloses the interchangeability of nutritional equivalents of amino acids, for example, the esters, amides, and salt derivatives thereof or precursors such as pepiones or peptides. Inclusion of these can result in slower absorption and consumption of greater amounts of digestive energy compared to the composition of the present invention, factors of great importance to, a high performance athlete. Other disadvantages of the use of the Winitz composition in the context of training and competition can be understood from the following

None of the prior art drinks can be used as the exclusive source of nutrition during periods of training or competition, as none of the available sports drinks will provide for substantially all of the nutritional of this invention, a "stress" condition exists when an individual's metabolic rate exceeds approximately 500 kcal per hour as a result of physical exertion, or, alternatively, when through sustained exertion an individual maintains a pulse rate in excess of 125 beats per minute for a period of 90 minutes or more. Additional nutrient sources are needed during long training sessions and competitions. As well as failing to provide for substantially all of the athlete's nutritional needs, known sports drinks are attended by a number of additional disadvantages.

One disadvantage of prior art formulations is the generally low gastrointestinal tolerance. Tolerance can be described as the capacity of the gastrointestinal tract to ingest and digest food. The proper balance of amino acids, carbohydrates, electrolytes, vitamins, minerals and trace elements creates the proper lumenal environment (e.g., osmolality, etc.) to prevent the flow of water and electrolytes into the lumen of the small bowel which may cause distention of the bowel, thus creating pressure, pain and cramps from increased peristalsis. Prior art products generally have a high osmotic load which creates an increasing fluid volume in the large bowel, causing diarrhea. Diarrhea causes dehydration and magnifies the electrolyte imbalance which has a catastrophic impact on athletes undergoing the stress of training and competition.

Presently available sources of nutrition for athletes are additionally not optimized to provide maximal rates of absorption. Foods that are slowly absorbed during digestion do not provide the body with immediate energy, whereas nutrients which quickly cross the mucosal membranes into the blood provide more immediate energy. Moreover, sports drinks and foods which require large amounts of digestive energy will not be optimally beneficial to the athlete during training and competition. During exercise, most of the blood is shunted or diverted from the gastrointestinal tract to the muscle groups performing the exercise. Hence, any diversion of blood back to the gastrointestinal track for digestion, which will result, for example, from a dist comprising fats or polypeptide protein, could reduce the blood available to the muscles, thereby diminishing performance. On the other hand, as a result of sustained exertion and physical stress, digestion of complex

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materials may proceed too slowly to provide adequate nutrition to the athlete during such exertion.

Another problem athletes face is familiarity with, and reproducibility of, their diet. It is well known that if an athlete eats something during training or competition that his body is not used to, performance will suffer.

Another important consideration in the design of a complete nutrient composition for athletes is the effect of stress upon the breakdown of muscle protein. Under conditions of stress there is an increased use of amino acids from muscle tissue as an energy source, and an increased percentage of total calories are supplied by the direct oxidation of the branched-chain amino acids leucine, isoleucine and valine. See, e.g., K.J. Fchott, J. Jahrmann, U. Potter, V. Neuhoff "On the Role of Branched Amino Acid in Protein Metabolism of Skeletal Muscis\*, Journal of Z Naturforsch, May-June 1985, line 40, pgs. 427-437; S.F. Lowry, G.D. Harowitz, D. Rose, M.F. Brennan \*Influence of Nutritional Status on Exertion Induced Forearm Amino Acid Metabolism in Normal Man", Journal of Surgical Research. May 1984, Vol. 36, pgs. 438445; D. Horst, N.D. Grace, H.D. Conn, E. Schiff, S. Schenker, A. Viteri, D. Law, C.E. Atterbury "Comparison of Dietary Protein With an Oral, Branched-Chain Enriched Amino Acid Supplement in Chronic Portal Systemic Encephalopathy\*, Journal of Hepatology, March-April 1984, Vol 4, pgs. 279-287; A.E. Harper, R.H. Miller, K.P. Block \*Branched-Chain Amino Acid Metabolism", Annual Review of Nutrition, 1984, Vol. 4, pgs. 409-454; and F.B. Cerra, J.E. Maouski, E. Chute, N. Newer, K. Teasley, J. Lysne, E.P. Shronts, S.N. Konstantinides "Branched-Chain Metabolic Support, a Prospective, Randomized, Double Blind Trial in Surgical Stress", Annals of Surgery. March 1984, Vol. 199, pgs. 288-291. Urinary excretion of nitrogen, resulting from the breakdown of muscle protein, is high during conditions of stress. Branched-chain amino acids exert a nitrogen retention effect when ingested during conditions of stress.

An additional disadvantage of the presently available sports drinks is that few have a palatable taste. Taste or palatability is an important parameter for a sports drink or nutrition source. Excellent taste is not easily achieved for a sports drink or nutrition source for an athlete as the sense of taste changes with the metabolic state of the individual.

Furthermore, standard methods for the preparation of known solid nutrient blends are inadequate for the more complex blends necessary for a complete nutrient composition for athletes. Standard methods of preparation of solid chemical blends typically involve simple weighing and blending steps. As an example, the most straightforward standard method of preparation of a solid chemical blend is a procedure involving the individual weighing of each of the raw materials followed by a simple mixing or milling of all of the solids together under low mixing speeds for a defined period of time. As the complexity of the composition increases, however, it has been discovered that more steps and unique methods of preparation are required, it was determined that the more streightforward methods for the preparation of solid nutrient blends could not achieve a final blend which could be rapidly and completely dissolved in tap water under ordinary use conditions. The fallure of these standard methods was caused mainly by the insolubility of several amino acids, particularly hydrophobic and aromatic amino acids, e.g., leucine, valine, phenylalanine, tryptophan, tyrosine, aspartic acid and glutamic acid.

Summary of the Invention

It is therefore an object of the present invention to provide a sports drink for athletes that meets substantially all of the nutritional requirements of a body under stress, can be chemically defined for reproducibility and user familiarity, provides an optimal training and competition diet that can be digested with minimal energy, and can be quickly absorbed. It is another object of the present invention to provide a sports drink as above which contains a high proportion of branched-chain amino acids, will not cause gastrointestinal intolerance or irritation, and has acceptable to good taste and palatability.

Still a further object of the present invention is to provide a dependable method for preparation of a nutrient composition, so that it will consistently achieve rapid and complete dissolution in tap water under ordinary use

In accomplishing the foregoing objects, there has been provided in accordance with one aspect of the present invention, a palatable, onlify ingestible nutrient blend, which provides substantially all of the nutritional, carbohydrate, and energy requirements of an athlete under conditions of physical stress, without interfering with fluid absorption or causing gastrointestinal disturbances. The blend comprises essential and preferably also nonessential amino acids, nutrient factors which may include vitamins, trace elements and minerals, and may also include carbohydrates, electrolytes and one or more flavoring alds. The flinal blend is water soluble and can supply, in a volume that may reasonably be ingested in one day, as much as about 10,000 or even 20,000 kcal. The amino acids contained in the blend exist in a substantially pure, free, unhydrolyzed stare and preferably the weight percent of the essential amino acids is high in relation to, and may exceed the weight percent of the non-essential amino acids. In addition to containing a high essential to non-essential amino acid calorie nitrogen ratio to satisfy caloric and protein synthesis requirements during stress. Particular mixtures of amino acids, carbohydrates and flavoring alds are used to achieve superior taste, and the diet will not cause gastrointestinal intolerance or irritation in the healthy individual.

In accordance with one embodiment of the present invention, there is provided a palatable, orally ingestible nutrient blend, comprising free essential and non-essential amino acids, nutrient factors, carbohydrates, electrolytes, and flavoring aids wherein the blend is water soluble in 6 minutes or less with simple stirring or shaking and provides substantially all of the nutritional, carbohydrate, and energy requirements of an athlete

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under conditions of physical stress, without interfering with fluid absorption or causing gastrointestinal disturbances. In the nutrient blend of the present invention, the total free amino acid content preferably comprises at least 20% by weight but not more than 45% by weight branched-chain emino acids. The free non-essential amino acids may advantageously be selected from the group consisting of L-Alanine, L-Arginine, L-Aspartic acid, L-Glutamic acid, aminoacetic acid, L-Histidine, L-Proline, L-Serine, L-Tyrosine, and L-Cysteine.

in accordance with a preferred embodiment of the nutrient blend of the present invention, the weight percent of each of the free essential amino acids, expressed as a fraction of total free amino acids, is:

3.00%-25.00% L-Isoleucine 2,20%-20.00% L-Leucine 10 4.00%-16.00% L-Valine L-Lysine 1.00%-14.00% 1.00%-11.00% L-Methionine 0.00%-5.00% L-Phenylalanine 1,40%-4,40% L-Threonine 15 0.00%-4.50% L-Tryptophan

It is also preferred that the weight percent of each of the nutrient free non-essential amino acids in the nutrient composition, expressed as a fraction of total free amino acids, is:

2.00%-15.00% L-Alanine 2.10%-2.40% L-Arginine 20 L-Aspartic Acid 0,30%-6.10% 0.00%-20.40% L-Glutamic Acid 1.70%-12.30% Aminoacetic Acid L-Histidine 2.10%-5.00% 3.00%-10.30% 25 L-Proline 2.00%-5.30% L-Serine 0.00%-4.30% L-Tyrosine 0.00%-1.50%. L-Cysteine

In a particularly preferred nutrient blend, the weight percent of each of the essential and non-essential free

30 amino acids is:

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L-Isoleucine 6.00%-18.00% L-Leucine 7.00%-19.00% L-Valine 10.00%-14.00% L-Lysine 10.00%-14.00%

L-Methionine 1.00%-5.00% L-Phenylelanine 0.00%-3.00%

2.00%-4.00% L-Threonine L-Tryptophan 0.00%-4.00% 7.00%-11.00% L-Alanine 6.00%-10.00% L-Arginine L-Aspartic Acid 0.30%-3.00% L-Glutamic Acid 0.00%-6.50% Aminoacetic Acid 4,00%-6.00% L-Histidine 2.10%-4.00% 7.00%-10.00%

L-Proline 7,00%-10,00% L-Sarlna 2,00%-3,00% L-Tyrosine 0,00%-1,20% L-Cystine 0,00%-0,70%

In some preferred embodiments of the nutrient blend, the nutrient factors are selected from the group consisting of vitamin A, vitamin D3, vitamin E, vitamin C, folic acid, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, biotin, pantothenic acid, vitamin K1, chlorine, calcium, phosphorus, todine, Iron, magnesium, copper, zinc, manganese, selenium, molybdenum, chromium; the electrolytes are selected from the group consisting of sodium chloride, potassium acetate sodium phosphate, and calcium gluconate; and the carbohydrates are selected from the group consisting of sucrose, glucose, dextrose, fructose, polyglucose, maltodextrin, and corn syrup.

In another preferred embodiment of the nutrient blend, the nutrient factors in a portion thereof containing 16 g free amino acid are present in an amount of:

1,000-7,500 IU Vitamin A 150-600 IU Vitamin D3 Vitamin E 10-45 IU 90-400 mg Vitamin C Folic acid 0.5-2 mg 2.3-6 mg Thiamlne Riboflavin 2.6-8 mg 15-60 mg Niacin Vitamin B6 1.5-6 mg 85

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Vitamin B12 3-50 mcg	
Blotin 0.25-1.8 mg	
Pantotheric acid 7.5-90 mg	
Vitamin K1 5-60 mcg	5
Chlorine 50-300 mg	•
Calcium 0.4-4 g Phosphorus 0.25-2 g	
lodine 50-325 mcg	
Iron 3-325 mg	
Magnesium 100-600 mg	10
Copper 0.75-6 mg	
Zinc 9-220 mg	
Manganese 0.6-4 mg	
Selenium 20-150 mcg	
Molybdanum 20-150 mcg	15
Chromium 10-100 mcg.	
In addition, the electrolytes, in a portion of said blend which contains 16 g free amino acids, are preferably	
present in amounts of:	
Sodium Chloride 20-160 mEq	20
Potassium Chloride 1-80 mEq Potassium Acetate 5-60 mEq	
Sodium Phosphate 1-30 mMol	
Calcium Gluconate 0.46-20 mEq;	
the carbohydrates are preferably present in amounts of:	
Sucrose 20-100 grams	25
Glucose 10-40 grams	
Dextrose 10-60 grams	
Fructose 10-40 grams	
Poly-Glucose 60-180 grams	30
Maîto-Dextrin 90-250 grams	30
Corn Syrup 50-120 grams;	
and the flavoring aids are preferably present in amounts of:	
Cocoa 20-85 grams Carob Powder 20-125 grams	
Vanilla Extract 0.25-2 grams	35
Powdered Non-Fat Milk 0-400 grams.	
in one particularly preferred nutrient composition according to the present invention, the amino acids,	
expressed as a weight percent of 16 g total free amino acids, comprise:	
L-Isoleucine 15.50% ± 2%	
L-Leucine 16.00% ±2%	40
L-Valine 10.69% ±2%	
L-Lysine 13.92% ±2%	
L-Methionine 2.10% ± 1%	
L-Phenytalanine 0.41% ±0.2%	45
L-Threonine 2.80% ±1.5%  L-Tryptophan 1.02% ±0.5%	-10
L-Alanina 9.30% ±2%	
L-Arginine 8.22% ±2%	
L-Aspartic Acid 0.32% ±0.15%	
Aminoacetic Acid 3.91% ±1.8%	50
L-Histidine 4.02% ±2%	
L-Proline 8.38% ±2%	
L-Serine 2.39% ±1%	
L-Tyrosine 0.47% ±0.2%	55
L-Cysteine 0.45% ±0.2%;	33
the nutrient factors are present in the amounts of:	
Vitamin A 1.500.00 IU Vitamin D3 120.00 IU	
Vitamin D3 120.00 IU Vitamin E 9.00 IU	
Vitamin C 36.00 mg	60
Folic acid 0.24 mg	
Thlamine 0.90 mg	
Riboflavin 1.20 mg	
Niacin 12.00 mg	
Vitamin B6 1.20 mg	65

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Vitamin B12 9.60 mcg Biotin 3.00 mg 6.00 mg Pantothenic acid Vitamin K1 13.40 mcg Chlorine 44.20 mcg Calcium 300.00 mg Phosphorous 300.00 mg lodine 45.00 mcg Magnesium 120.00 mg 0.60 mg 10 Copper Zinc 6.00 mg 562.00 mcg Manganese Selenium 30.00 mcg Molybdenum 30.00 mcg Chromium 10.00 mcg; 15 Iron 4.80 mg;

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the electrolytes are present in amounts of:

Sodium Chloride 20.50 mEq
Potessium Chloride 6.70 mEq
Calcium Gluconate 6.97 mEq
Sodium Phosphate 7.24 mMol

Sodium Phosphate 7:24 mMol Ascorbic Acid 1000 mg;

the carbohydrates are present in amounts of:

Sucrose 25 grams
Fructose 5 grams
Dextrose 59 grams
Malto-Dextrin 211 grams; and
the flavoring aids are present in amounts of:

Cocoa 50 grams

Non-Fat Dry Milk 90 grams.

In accordance with another aspect of the present invention, there is provided a method for the preparation of a water-soluble, palatable, orally ingestible nutrient blend, comprising the steps of: (a) dry blending a first mixture comprising substantially pure free essential and non-essential amino acids until a transition from discrete crystals to a fine, amorphous powder appearance is achieved; and thereafter (b) blending the first mixture with additives selected from the group consisting of: vitamins, trace elements, minerals, simple and complex carbohydrates, electrolytes, and flavoring aids, until a uniform consistency is achieved.

In accordance with still another aspect of the present invention there is provided a method for the preparation of a water soluble nutrient blend, comprising the steps of: (a) blending a first mixture of free amino acids under conditions that cause a transformation from discrete crystals to a fine amorphous powder; (b) blending a second mixture of nutrient factors under conditions that yield a uniform particle size of between about 10 and 20 microns; and (c) blending the first and second mixtures together with at least one additive selected from the group consisting of carbohydrates, electrolytes and flavoring alds, until a homogeneous powder is achieved.

Finally, the present invention also includes a method of meeting the nutritional requirements of an athlete, comprising orally administering to an athlete undergoing physical stress a composition as described above, thereby providing substantially all of the nutritional, carbohydrate, and energy requirements of said athlete under conditions of physical stress without interfering with fluid absorption or causing gastrointestinal disturbances.

Brief Description of the Drawings

Figure 1 is a graph of the data relating to changes in percentage body fat and lean body mass reported in Example 7.

Detailed Description of the Invention

Current research on amino acids has disclosed that high branched-chain amino acids, including valine, leucine, and isoleucine, are required to maintain and repair cellular integrity in the stressed marathon athlete. See authorities cited supra. It is further recognized that cartain combinations of these high branched-chain amino acids are significantly more beneficial in maintaining cellular integrity and repair than others. On the other hand, the branched-chain amino acid component also affects the palatability of the nutrient composition. Valine, for example, imparts an undesirable flavor to the composition. Thus, the composition of the present invention has been carefully optimized in light of competing objectives. The weight percentages of branched-chain amino acids for Experiments 1-5 (infra), as a percentage of total amino acids, are illustrated in Table 1.

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# TABLE 1

# Proportion of Branched Chain Amino Acids. as a Weight Percent of Total Amino Acids

			_	•
•		Invention	Prior Art	
Example	1	22.5%	13.6%	
Example		40.2%	13.4%	10
Example		27.2%	15.4%	
Example		42.19%	15.1%	
Example		27.2%	15.4%	15
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This table illustrates the percentage of branched-chain amino acids in the Examples of the present invention, and, for comparison, the table illustrates the same calculations performed on some of the examples contained in U.S. Patent No. 3,697,287. As can be seen, the prior art compositions consistently exhibit a lower component of branched chain amino acids. This is so not only because that disclosure does not recognize the benefits of increasing the branched chain component, but also because that disclosure teaches that the amino acid profile should approximate that naturally occurring in such foods as meat, eggs, or milk.

Identifying proper combinations of branched-chain amino acids and achieving proper methods of combining high branched-chain amino acids are not easy tasks. For example, the high percentage of isoleucina in Example 2 appears to have caused the lower gastrointestinal tolerance of that composition. Example 4, which has a greater overall content of branched-chain amino acids, tasted just as good but did not cause gastrointestinal disturbances.

Several things are essential to achieve a good-tasting composition: (1) the ratio of amino acids, (2) the total amount of amino acids per dosa, and (3) the amount of flavoring aids and carbohydrates necessary to offset or mask the poor taste of the amino acids. Numerous flavoring aids are known, which may be used either individually or in combination.

Table 2 contains the results of organoleptic evaluations of the five formulations represented by Examples 1-5. These evaluations were performed by a small group of marathon bicyclists who were given an unknown composition and asked to rate it on a scale of from good to terrible. A good rating meant that the composition was pleasant and generally acceptable. A fair rating meant that the composition was bland or neutral but was not objectionable. A poor rating meant that the composition had some flavor defect such as a somewhat objectionable bitter aftertaste. A terrible rating meant that the composition was so objectionable that it was rendered unpalatable.

In these examples, the amino acids were separated into two groups. The first group of amino acids consisting of isoleucine, leucine, methionine, threonine, alanine, glutamic acid, glycine, serine, and tyrosine, comprise the good to bland or neutral tasting amino acids. The second group of amino acids consists of valine, lysine, phenylelanine, tryptophan, arginine, aspartic acid, histidine, proline, and cysteine. It is this latter group for which the flavoring aids become most critical.

Separation of specific amino acids into flavor groups was accomplished through a separate taste test than the one previously described. In this taste test, a panel of about twenty volunteer testers was presented with unknowns which were evaluated for such characteristics as bitter, sweet, bland, or other, including unpelatable. A remarkably high level of agreement among the testers was observed when reviewing the test results pertaining to which amino acids were good, unacceptable, etc. The results were also remarkably consistent with the results from the taste test on the final blends, discussed supra. In other words, a bland containing a high concentration of "bad" tasting individual amino acids also exhibited a bad taste.

The taste test results for Example 3 demonstrate that when the percentage of bad to terrible tasting amino acids reaches 60.2%, they require the greatest amount of flavoring sides to make the mixture palatable. This is further illustrated by Example 5, using a composition which is identical to that of Example 3 except that the flavoring sides are significantly decreased to an amount comparable to the flavoring aid content of the Example 2 composition. It should be noted that whereas the Example 2 composition was good tasting, the Example 5 composition was barely acceptable. Additionally, the Example 2 mixture tastes better than the composition of Example 3, because the Example 2 mixture contains 72.4% of the good to bland tasting amino acids, whereas the Example 3 formulation contains only 39.8% of those amino acids. This relationship between taste and amino acid makeup holds true despite the fact that the Example 3 formulation contains a higher concentration of flavoring sides than does that of Example 2.

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TABLE 2

AMINO ACID COMPOSITION AND PALATABILITY OF EXAMPLES

EX 1 EX 2 EX 3 EX 4 EX 5

Overall Taste Results:	Good	Good	Fair	Good	Poor
Group 1 : Go	ood to Bla	nd Tasti	ng Indiv	idual Am	ino Acids
% Ile	6.10%	25.00%	3.00%	15.50%	3.00%
% Leu *	9.20%	2.20%	8.20%	16.00%	8.20%
% Met	3.40%	10.80%	6.80%	2.10%	6.80%
% Thr	4.40%	2.40%	1.40%	2.90%	1.40%
% Ala	2.00%	15.00%	4.00%	9.30%	4.00%
* Glu	20.40%	0.00%	6.50%	0.00%	6.50%
% Gly	1.70%	12.30%	6.30%	3.91%	6.30%
% Ser	5.30%	2.00%	3.00%	2.39%	3.00%
% Tyr	4.30%	_0.00%	0.60%	0.47%	0,60%
-	56.80%	72.40%	39.80%	52.57%	39.80%

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Overall						
<b>Taste</b>						
Results:	Good	Good	Fair	Good	Poor	
Group 2: Ba	d to Terr	ible Tas	ting Ind	ividual .	Amino Acids	
% Val *	7.20%	13.00%	16.00%	10.69%	16.00%	
% Lys	8.20%	1.00%	9.30%	13.92%	9.30%	
% Phe	5.00%	0.00%	0.50%	0.41%	0.50%	
% Trp	1.20%	0.50%	3.50%	1.02%	3.50%	
t Arg	3.10%	2.10%	20.40%	8.22%	20.40%	
asp	6.10%	1.00%	4.20%	0.32%	4.20%	
% His	2.10%	2.10%	3.20%	4.02%	3.20%	
% Pro	10.30%	10.00%	3.00%	8.38%	3.00%	
% Cys	0.001	0.60%	0.00%	0.45%	0.00%	
	43.20%	27.60%	60.20%	47.43%	60.20%	
Flavoring A	ids				·	•
Carob	90 g					
Cocoa	0 g	56 g	155 g	50 g	56 g	
NF-Milk	270 g	150 g	380 g	90 g	150 g	
					·	
Carbohydrat	e Sources					
Sucrose	100 g	30 g	110 g	25 g	110 <sup>.</sup> g	
Fructose	20 g	0 g	0 g	5 g	0 g	
Glucose	10 g	0 g	0 g		0 g	
Dextrose	0 g	20 g	40 g	59 g	40 g	•
Poly-Glu	0 g	10 g	130 g	0 g	130 g	
Corn Syr	o g	183 g	0 g	0 g	0 g	
Lodex	100 g	0 g	οg	211 g	0 g	

<sup>\*</sup>Designates High Branched Chain Amino Acids

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The composition made in accordance with the present invention can be digested with minimal energy. Since the nutrients are supplied by the invention in simple, readily available form, e.g., free amino acids, minimal

digestive energy with maximal absorption is possible. As used in this application, the term "free amino acid" means monomeric amino acids or salts thereof but not the mixtures of amino acids that result from hydrolysis of a protein source. The use of a free amino acid source instead of a polypeptide protein source conserves energy, because polypeptide protein sources require energy to be enzymatically hydrolyzed. When digestive energy is conserved, more energy is available to be used for other functions in the athlete's body. Moreover, the high proportion of branched chain amino acids of the present invention helps to satisfy caloric and protein synthesis requirements during stress. Finally, the amino acids used in the present invention should be substantially free of impurities such as mercaptans, which could adversely affect the flavor of the composition.

Another beneficial result of the particular balance of ingredients in the claimed composition of the present invention is that these compositions exert a minimal osmotic effect on the gastrointestinal tract, thus preventing any fluid shifts. Fluid shifts can result in electrolyte and water imbalances that can lead to distension, cramping, nausea, and diarrhea. The compositions of the present invention can also be quickly absorbed, for the most part, in the stomach, the duodenum and the upper jejunum. Due to the unique properties of the compositions, almost all of the materials pass directly through the intestinal membranes, and are thus immediately available for replacing and maintaining the physiological demands of the stressed athlete. In this regard, it is desirable to minimize the fat content in the composition of the present invention. Fats are generally digested and absorbed relatively slowly, and may interfere with the breakdown and absorption of other dietary elements in the composition. In addition, fat is a relatively low efficiency energy source and is not well tolerated by the gastrointestinal tract of an athlete under physical stress. Thus, because the fat content of the present composition is minimized, gastric emptying is not delayed, blood shunted to the peritoneal region is minimal, and, as a result, more energy is available for use by the other body functions of the stressed athlete.

Thus, in accordance with the foregoing considerations, it has been determined that compositions meeting the foregoing objectives will have an armino acid profile in which the branched chain amino acids, as a percentage by weight of total free amino acids in the composition, comprise at least about 20% by weight, preferably at least about 25% by weight, and more preferably at least about 30% by weight. The branched chain amino acid content as a percentage by weight of total free amino acids in the composition should not exceed about 60% by weight, more preferably should not exceed about 45% by weight, and most preferably should not exceed about 40% by weight.

The composition of the present invention should include all of the essential amino acids in free form, and preferably includes the nonessential amino acids. The essential amino acids as used herein are L-isoleucine, L-teucine, L-valine, L-tysine, L-methionine, L-phenylalanine, L-threonine, and L-tryptophan. The nonessential amino acids, as used herein, refer to L-alanine, L-arginine, L-aspartic acid, L-glutamic acid, L-aminoacetio acid, L-histidine, L-proline, L-serine, L-tyrosine, and L-cysteine.

Also included in the composition of the present invention are nutrient factors such as vitamins and similar compounds, specifically vitamin A, vitamin D3, vitamin C, vitamin E, folic acid, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, blotin, pantothenic acid, and vitamin K1.

The composition of the present invention also should contain appropriate amounts of the electrolytes, including sodium, potassium, chloride, calcium, and phosphate.

The compositions of the present invention may also include minerals and trace elements, including Iron, magnesium, copper, zinc, manganese, selenium, molybdenum, chromium, and iodide.

These compositions also include carbohydrates which serve as one of the principal caloric sources, in addition to the branched-chain amino acids, for athletes using the composition. The carbohydrate content of the composition is preferably a combination of simple and complex saccharides. The simple sugars, or monosaccharides, may be glucose, dextrose, fructose, or corn syrup. The disaccharide used is preferably sucrose, but other disaccharides may be used. Finally, the complex carbohydrates used may include such moleties as polyglucose and malto-dextrin. The simple saccharides generally provide the most immediate energy to the athlete, but if the entire caloric content of the composition is, for example, in glucose, the resulting fluctuations in serum glucose level after ingestion of the composition may be unsatisfactory. Accordingly, the preferred composition will include a mixture of carbohydrates to provide sustained energy source and a more stable blood glucose level.

The flavoring alds used in the present invention may be any conventional flavoring alds that provide a pleasant-tasting composition when combined with the remainder of the ingredients. Conventional flavoring aids include natural or artificial graps, cherry, lemon, lime, punch, root beer, orange, grapefruit, strawberry, and other flavorings. The suitability of any particular flavoring aid in any particular composition of the present invention may be readily ascertained by means of a simple taste test. The preferred flavoring aids are cocoa, carob powder, vanilla extract, and powdered nonfat milk.

The composition of the present invention may advantageously be provided in unit dosage packages suitable for mixing with between 250 ml and 2.1 of water or other liquid to provide a drink having an energy density of at least about 350 kcal per liter, preferably greater than about 400 kcal per liter and more preferably in excess of about 600 kcal per liter, wherein the net dry weight of a unit dosage package is from about 30 g to about 600 g, and preferably from about 80 g to about 120 g. In determining a desirable energy density for the final product, it is recognized that too low a density (e.g., too much water) can result in diarrhea, and can also require the athlete to ingest a greater fluid volume than is desirable in order to satisfy nutritional and caloric requirements. On the other hand, too high an energy density might supply insufficient fluid volume, might have too high an osmolality, causing gastric disturbances, and might also adversely affect palatability of the composition.

Certain specific ingredients that may be included in the composition of the present invention, together with ranges of those ingredients meeting the criteria discussed above, are set forth in Table 3.

# TABLE 3 GENERAL COMPOSITION

Ingredient	Range	Preferred Range	10
Amino Acid			
L-Isoleucine	3.00% - 25.00%	6.00% - 18.00%	
L-Leucine	2.20% - 20.00%	7.00% - 19.00%	15
L-Valine	4.00% - 16.00%	10.00% - 14.00%	
L-Lysine	1.00% - 14.00%	10.00% - 14.00%	
L-Methionine	1.00% - 11.00%	1.00% - 5.00%	20
L-Phenylalanine	0.00% - 5.00%	0.00% - 3.00%	
L-Threonine	1.40% - 4.40%	2.00% - 4.00%	
L-Tryptophan	0.00% - 4.50%	0.00% - 4.00%	25
L-Alanine	2.00% - 15.00%	7.00% - 11.00%	
L-Arginine	2.10% - 20.40%	6.00% - 10.00%	
I-Aspartic Acid	0.30% - 6.10%	0.30% - 3.00%	30

L-Glutamic Acid	0.00% -	20.4	0\$	\$00.0	- 6.	50%
Aminoacetic Acid	1.70% -	12.3	0%	4.00%	- 6.	\$00
L-Histidine	2.10% -	5.0	<b>8</b> 0	2.10%	÷ 4.	\$00
L-Proline	3.00% ~	10.3	\$0	7.00%	<del>.</del> 10.	800
L-Serine	2.00% -	5.3	0\$	2.00%	- 3.	\$00
L-Tyrosine	0.00% -	4.3	80	0.00%	- 1.	20₺
L-Cysteine	0.00% -	1.5	\$0	0.00%	- 0.	70%
<u>-</u>						
Vitamin. Mineral &	Trace Eleme	nt		•		
Vitamin A	1000 -	7500	IU	3750 -	7500	IU
Vitamin D3	150 -	600	IU	300 -	600	IU
Vitamin E	10 -	45	w	22 -	45	IU
Vitamin C	90 <sub>:</sub> -	400	ng	190 -	400	mg
Folic Acid	0.5 -	2	mg	0.6 -	1.2	mg
Thiamine	2.3 -	6	ng	4.5 -	6.0	mg
Riboflavin	2.6 -	8	. mg	5.1 -	7.0	mg
Niacin	15 -	60	ng	30 -	60	mg
Vitamin B6	1.5 -	6	ng	3 -	6.0	mg
Vitamin B12	3 -	50	ncg	9 -	20	ncg
Biotin	0.25 -	1.8	mg	0.9 -	1.8	mg
Pantothenic Acid	7.5 -	90	mg	15 -	60	mg
Vitamin Kl	5 🕶	60	ncg	30 -	40	mcg
Chlorine	50 -	300	mg	50 <b>-</b>	221	mg
Calcium	0.4 -	. 4	g	0.75 -	1.5	g
Phosphorus	0.25 -	2	g	0.75 -	1.5	g
Iodine	50 -	325	ncg	50 -	225	ncg
Iron	3 -	325	mg	14 -	40	mg
Magnesium	100 -	600	mg	150 -	600	mg
Copper	0.75 -	6	ng	1.5 -	3	mg
zinc	9 -	220	ng	18 -	36	mg
Manganese	0.6 -	4	mg	1.40 -	2.8	ng
Selenium	20 -	150	ncg	75 -	150	ncg
Molybdenum	20 -	150	ncg	75 <b>-</b>	150	ncg
Chromium	10 -	100	mcg	25 -	60	ncg

Electrolytes							
Sodium Chloride	20 ~	160	mEq	50 -	15	mEq	
Potassium Chloride	1 -	80	mEq	15 -	40	mEq	5
Potassium Acetate	5 -	60	mMol	10 -	29	mMol	
Sodium Phosphate	1	30	mMol	5 -	20	mMol'	
Calcium Gluconate	0.46 -	20	meq	2 -	8	mEq	10
<u>Carbohydrates</u>	•						
Sucrose	5 -	- 110	grams	20 -	100	grams	15
Glucose	0 -	- 60	grams	10 -	40	grams	
Dextrose	0 -	- 80	grams	10 -	. 60	grams	
Fructose	0 -	- 100	grams	10 -	40	grams	20
Poly-Glucose	0 -	- 250	grams	60 -	180	grams	:
Lodex 10 DE							
(Malto-Dextrin)	0 -	- 300	grams	90 -	250	grams	25
Corn Syrup	0 -	- 184	grams	50 -	120	grams	
Flavoring Aids							
Hershey's Cocoa	20 -	- 85	grams	45 -	- 65	grams	
Carob Powder	20 -	- 125	grams	60 -	125	grams	
Vanilla Extract	0.25 -	- 2	grams	0.5	<b>- 1.</b>	2 grams	35
Powdered Non-fat Milk	0 -	- 400	grams	80 -	- 220	grams	

According to one application of the method of the present invention, a first mixture of free amino acids is dry blended until a transformation from discrete crystals to a fine amorphous uniform powder appearance is achieved. It has been observed that this transition from crystalline to amorphous form occurred at temperatures in excess of about 40°C generated by blending action, preferably, the first mixture of amino acids is blended under high shear conditions at speeds of at least about 15,000 rpm, preferably in excess of about 19,000 rpm, and most preferably from approximately 19,000 rpm to about 22,000 rpm. This first mixture of free amino acids is preferably blended for at least about one minute, more preferably in excess of 2.5 minutes and most preferably from about 2.5 to about 4.5 minutes. If this procedure is not followed, some of the individual amino acids will not go into solution upon reconstitution with water and will either float on the top or precipitate out.

A second mixture comprising nutrient factors is prepared, preferably by dry blending the nutrient factors in a powder mill until well mixed. The dry blending is preferably effected under conditions which, by application of shearing forces, yield a uniform particle size of less than about 30 microns, and more preferably from about 10 to 20 microns. The milling action takes these various materials which would otherwise not be blendable, and enables the production of a final, water soluble, homogeneous powder. The two mixtures are then combined together with any carbohydrates, electrolytes and flavoring alds and blended until a uniform consistency is achieved. This final blending may require more than about 20 minutes and perhaps as much as 40 minutes or more. The final blend is packaged appropriately and reconstituted with tap water just prior to use. The most important aspect of the method according to the present invention is the blending of the free amino acids in a distinct step under the conditions indicated. Although preparation of the second mixture has been disclosed as a distinct step, it may be possible to combine that step with the final mixing of all of the ingredients and still accrue the advantage of the present invention.

The invention may be more fully appreciated by reference to the appended examples. In each of Examples 1-5 which follow, the amino acids used are free, pure amino acids. The total percentage of each essential and non-essential emino acid for each example is given. Example 4, the composition preferred by marathon cyclists, has the highest percentage of total essential amino acids. Correspondingly, it has the lowest

percentage of non-essential amino acids.

The various ranges of each of the ingredients used in the Examples is summarized in Table 3, supra. The preferred ranges are also shown for each ingredient. Each Ingredient was not used in every one of Examples 1-5. For the specific composition of each formulation, refer back to the Examples.

**EXAMPLE 1** 

in this example, 18 grams of free amino acids in amounts corresponding to the stated weight percentages were dry blended at speeds of between about 19,000 and 22,000 RPM, using a Waring model No. 34BL22 blender, for a period of between about 2.5 and 4.5 minutes, until a transition from separate discrete crystals to a fine amorphous uniform powder appearance was achieved. Next, the indicated amounts of vitamins, trace elements, and minerals were mixed in a dry blender until the milling action reduced these materials to a particle size of between about 10 and 20 microns. Thereafter, the indicated amounts of carbohydrates, electrolytes and flavoring alds were weighed and all of the ingredients were blanded in a Patterson Kelley twin-shell model No. LB-16S liquids/solids blender-granulator, equipped with an intensifier bar, for a period of approximately 20-40 minutes. Finally, the blend was brought up to two liters final volume with water, and taste tested. The composition exhibited a good taste.

Amino Acid Profile based on 18 grams total Amino Acids

20	Amino Acid	*	Total	Amino	Acids
	Essential				
	L-Isoleucine				6.10%
25	L-Leucine				9.20%
	L-Valine		-		7.20%
	L-Lysine				8.20%

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L-Methionine	3.40%
L-Phenylalanine	5.00%
L-Threonine	4.40%
L-Tryptophan	1.20%
Total essential amino acids	44.70%
·	
Non-Essential	
L-Alanine	2.00%
L-Arginine	3.10%
L-Aspartic Acid	6.10%
L-Glutamic Acid	20.40%
Aminoacetic Acid	1.70%
L-Histidine	2.10%
L-Proline	10.30%
L-Serine	5.30%
L-Tyrosine	4.30%
Total non-essential amino acids	55.30%

Vitamin, Mineral & Trace F	% US RDA	
	7500 IU	150
Vitamin A		
Vitamin D3	600 IU	150
Vitamin E	45 IU	150
Vitamin C	380 mg	633
Folic Acid	1.2 mg	300
Thiamine	4.5 mg	300
Riboflavin	5.1 mg	300
Niacin	60 mg	300
Vitamin B6	6 mg	300
Vitamin B12	18 mcg	300
Biotin	0.9 mg	300
Pantothenic Acid	30 mg	300
Vitamin Kl	67 mcg	*
Chlorine	221 mg	<b>±</b>
Calcium	1.5 g	150
Phosphorus	1.5 g	150

	- Iodine	225 mcg .	150
	Iron	27 mg	. 150
5	Magnesium	600 mg	150
3	Copper	3 mg	150
	Zinc	36 mg	240
10	Manganese	2.81 mg	*
10	Selenium	150 mcg	*
	Molybdenum	150 mcg	*
15	Chromium	50 mcg	*
75	*No U.S. RDA established		
20	Electrolytes Chart	•	
	Sodium Chloride	90 mEq	
	Potassium Chloride	40 mEq	
25	Carbohydrate Chart		
	Sucrose	100 grams	
30	Fructose	20 grams	
W	Lodex 10 DE (Malto-Dextrin)	100 grams	
	Glucose	10 grams	
<i>35</i>			-
	Flavoring Aids		
	Carob Powder	90 grams	
40	Non-Fat Dry Milk	270 grams	•

# 45 EXAMPLE 2

The following composition was prepared in the same way as set forth in Example 1 to make two liters of final composition. In this Example, the vitamin, mineral and trace element composition remained the same as in Example 1. However, the amount of NaCl was decreased from 90 mEq to 88 mEq. Sucrose was reduced from 100g to 30g. 20g of dextrose, 183g of corn syrup, and 10g of poly glucose were added. Fructose and Lodex 10 DE were omitted. Also, the flavoring aids were changed as indicated. Upon taste testing, this mixture was determined to have good palatability.

Amino Acid Profile based on 28 grams total Amino Acids

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Amino Acid % Total Amino Acids E	ssential	
L-Isoleucine	25.00%	
L-Leucine	2.20%	
L-Valine	13.00%	•
L-Lysine	1.00%	
L-Methionine	10.80%	
L-Threonine	2.40%	
L-Tryptophan	0.50%	
Total essential amino acids	54.90%	
Non-Essential	•	
L-Alanine	15.00%	
L-Arginine	2.10%	
L-Aspartic Acid	1.00%	
Aminoacetic Acid	12.30%	
L-Histidine	2.10%	
L-Proline	10.00%	
L-Serine	2.00%	
L-Cysteine	0.60%	
Total non-essential amino acids	45.10%	٠
Vitamin. Mineral & Trace Element	<u>ts</u>	% US RDA
Vitamin A	7500 IU	150
Vitamin D3	600 IU	150
Vitamin E	45 IU	150
Vitamin C	380 mg	633
Folic Acid	1.2 mg	300
Thiamine	4.5 mg	300
Riboflavin	5.1 mg	300
Niacin	60 mg	300
Vitamin B6	6 mg	300
Vitamin B12	18 mcg	300

Biotin	0.9 mg	300
Pantothenic Acid	30 mg	. 300
Vitamin Kl	67 mcg	*
Chlorine	221 mg	*
Calcium	1.5 g	150
Phosphorus	1.5 g	150
Iodine	225 mcg	150
Iron	27 mg	150
Magnesium	600 mg	150
Copper	3 mg	150
Zinc	36 mg	240
Manganese	2.81 mg	*
Selenium :	150 mcg	*
Molybdenum	150 mcg	*
Chromium	50 mcg	*
*No U.S. RDA established		
Electrolytes Chart		
Sodium Chloride	88 mEq	
Potassium Acetate	40 mEq	
Carbohydrate Chart		•
Sucrose	30 grams	
Dextrose	20 grams	•
Corn Syrup	183 grams	
Poly-Glucose	10 grams .	
Flavoring Aids		
Hershey's Cocoa	56 grams	
Powdered Milk	150 grams	

# EXAMPLE 3

In Example 3, prepared in a similar manner to the foregoing examples to make two liters of composition, all of the vitarnins, minerals, and trace elements were reduced by one-half. NaCl was increased to 138 mEq and 5 mEq of calcium gluconate was added. Sucrose was increased to 110 g, dextrose increased to 40 g, and poly-glucose to 130 g. In this example, Hershey's cocoa was increased to 155 g, and non-fat dry powdered milk increased to 380 grams. This example exhibited only fair palatability.

Amino Acid Profile based on 11 grams total Amino Acids

Amino Acid % To	tal Amino Acids	10
Essential		
L-Isoleucine	3.00%	15
L-Leucine	8.20%	
L-Valine	16.00%	
L-Lysine	9.30%	20
L-Methionine	6.80%	
L-Phenylalanine	0.50%	
L-Threonine	1.40%	25
L-Tryptophan	3.50%	
Total essential amino ac	ids 48.70%	
		30
Non-Essential		
L-Alanine	4.00%	
L-Arginine	20.40%	35
L-Aspartic Acid	4.30%	
L-Glutamic Acid	6.50%	
Aminoacetic Acid	6.30%	40
L-Histidine	3.20%	
L-Proline	3.00%	
L-Serine	3.00%	45
L-Tyrosine	0.60%	
Total non-essential amin	no acids 51.30%	
		. 50

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Vitamin, Mineral & Trace Ele	\$ US RDA	
Vitamin A	3750 IU	75
Vitamin D3	300 IU	÷ 75
Vitamin E	22.5 IU	75
Vitamin C	190.0 mg	317
Folic Acid	0.6 mg	150
Thiamine	2.3 mg	150
Riboflavin	2.6 mg	150
Niacin	30 mg	150
Vitamin B6	3 mg	150
Vitamin B12	9 mcg	150
Biotin	0.5 mg	150
Pantothenic Acid	15 mg	150
Vitamin Kl	34 mcg	*
Chlorine	111 mg	. *
Calcium	0.75 g	75
Phosphorus	0.75 g	75 ·
Iodine .	113 mcg	75
Iron	14 mg	75
Magnesium	300 mg	75
Copper	1.5 mg	75
Zinc	18 mg	120
Manganese	1.40 mg	*
Selenium	75 mcg	*
Molybdenum	75 mcg	*
Chromium	25 mcg	*
*No U.S. RDA established		
Electrolytes Chart		
Sodium Chloride	138 mEq	
Potassium Chloride	40 mEq	
Calcium Gluconate	5 mEq	

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Carbohydrate Chart			
Sucrose	110	grams	
Dextrose	40	grams	5
Poly-Glucose	130	grams	•
Flavoring Aids			10
Hershey's Cocoa	155	grams	
Powdered Milk	380	grams	
			15
EVANDLE 4	6,		
EXAMPLE 4  Example 4 was also prepared in a manner composition in this example was favored by mainth a composition had the highest percentage of percentage of total non-essential amino acidatements were reduced to 30% of the U.S. R. reduced to 6.70 mEq. Calcium gluconate was a 1000 mg ascorbic acid were added. The carbo	rathon cyclists, and we of total essential amine s. In this example, mandally. D.A. Sodium chloride increased to 6.97 mEd	as considered to exhibit good palatability, or acids, and correspondingly, the lowest ost of the vitamins, minerals, and trace was reduced to 20.5 mEq, and KCI was a not 7.24 mMol sodium phosphate and	20
example.			25
Amino Acid Profile based on 16 grams total	Amino Acids		
Amino Acid	Total Amino	Acids	
Essential			30
L-Isoleucine		15.50%	45
L-Leucine		16.00%	35
L-Valine		10.69%	
L-Lysine		13.92%	40
L-Methionine		2.10%	10
			45
			50
			55
			60
· ·			

L-Phenylalanine	0.41%
L-Threonine	2.90%
L-Tryptophan	1.02%
Total essential amino acids	62.54%
Non-Essential	
L-Alanine	9.30%
L-Arginine	8.22%
L-Aspartic Acid	0.32%
Aminoacetic Acid	3.91%
L-Histidine	4.02%
L-Proline	8.38%
L-serine :	2.39%
L-Tyrosine	0.47%
L-Cysteine	0.45%
Total non-essential amino acids	37.46%

Vitamin, Mineral & Trac	% US RDA	
Vitamin A	1500.00 IU	30.0%
Vitamin D3	120.00 IU	30.0%
Vitamin E	9.00 IU	30.0%
Vitamin C	36.00 mg	60.0%
Folic Acid	0.24 mg	60.0%
Thiamine	0.90 mg	60.0%
Riboflavin	1.02 mg	60.0%
Niacin	12.00 mg	60.0%
Vitamin B6	1.20 mg	60.0%
Vitamin B12	3.60 mcg	60.0%
Biotin	3.00 mcg	60.0%
Pantothenic Acid	6.00 mg	60.0%
Vitamin Kl	13.40 mcg	*
Chlorine	44.20 mcg	*
Calcium	300.00 mg	30.0%
Phosphorous	300.00 mg	30.0%
Iodine	45.00 mcg	30.0%

Magnesium	120.00 mg	30.0%	
Copper	0.60 mg	30.0%	
Zinc	6.00 mg	40, 0%	5
Manganese	562.00 mcg	*	
Selenium	30.00 mcg	*	
Molybdenum	30.00 mcg	*	10
Chromium	10.00 mcg	•	
Iron	4.80 mg	30.00%	
*No U.S. RDA established.			15
Electrolytes Chart	•		
Sodium Chloride	20.50 mEq		20
Potassium Chloride	6.70 mEq	:	
Calcium Gluconate	6.97 mEq		
Sodium Phosphate	7.24 mMol		25
Ascorbic Acid	1000 mg	•	
Carbohydrate Chart		•	<i>30</i>
Sucrose	25 grams		
Fructose	5 grams		
Dextrose	59 grams		35
Lodex 10 DE (Malto-Dextrin)	211 grams		
Flavoring Aids		•	40
Hershey's Cocoa	50 grams		
Non-Fat Dry Milk	90 grams		
			45

#### EXAMPLE 5

This example was identical to Example 3, except that the Cocoa was reduced from 155 g to 58 g, and the non-fat powdered milk was reduced from 380 g to 150 g. These changes caused the palatability of the mixture to go from fair in Example 3 to poor in Example 5.

### **EXAMPLE 6**

In this experiment, the composition of Example 4 was dissolved in water at a ratio of approximately 116 grams of the solid to yield approximately 500 cc final composition, achieving an energy density of approximately 343 kcal per 500 cc of the final composition. This composition was Ingested by a marathon bicyclist during a 380 mile, non-stop training ride from Failbrook, California to Las Vegas, Nevada. The period of continuous exertion was approximately 22 hours and 20 minutes, during which period sufficient nutritional mixture to supply approximately 7,480 kcal was ingested. Blood analysis of samples obtained immediately prior to and following the trip yielded the following data:

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<u>Analyte</u>	Reference Range*	Pre-Ride	Post-Ride	_
Glucose	70-115	99	86	
Bun	10-25	27	32	
Creatinine	0.7-1.4	1.1	1.3	
Bun/Creatinine	10-30	24.5	24.6	
AST (SGOT)	1-50	48	<sub>,</sub> 61	
ALT (SGPT)	1-55	34	37	
GGTP	2-65	10	· 9	
Bilirubin	0-1.3	0.3	1.0	
Alk. Phos.	30-105	46	50	
Ca	9.0-11.0	9.3	10.2	
LDH	100-225	235	249	
Phosphorous	2.6-4.5	4.1	5.3	
Na	137-148	142	142	
ĸ	3.6-5.5	4.3	4-1	
Cl	98-108	105	102	
Uric Acid	2.5-8.0	5.0	3.7	
Triglyceride	50-200	57	48	2
Cholesterol	150-300	187	175	
Total Protein	6.0-8.0	6.1	6.2	5

Albumin	3.5-5.0	4.1	4.2	
Globulin	2.0-3.5	2.0	2.0	
A/G Ratio	1.1-2.3	2.1	2.1	5
Iron	50-210	121	88	
Ferritin	20-300	160	**	
Hgb	16.0±2	14.2	14.8	. 10
MCV	82-101	92	92	,,
MCH	27-34	31.5	31.5	
MCHC	34±2	34.2	34.1	15
WBC	7.5±3.5	7.5	7.4	
Mg-Serum	1.5~2.5	1.8	**	
Zn-Serum	60-130	92		20
Hct	47±5	41.4	43.5	
RBC	5.4±0.7	4.50	4.71	

\*Generally accepted normal values

\*\*Data not available

The rider was very pleased overall with the nutrient blend, and it did not cause any gastrointestinal disturbances or diarrhea.

These data demonstrate the remarkable ability of the compositions of the present invention, when used as a sole nutritional source, to maintain blood values of numerous important physiological substances within the normal range, despite sustained, extraordinary exertion. Particularly significant are the stable values for the electrolytes Na, Cl Ca, K, and phosphorus, which are ordinarily volatile in response to stress, and the uric acid and creatinine values, relating to protein breakdown and fluid balance.

# EXAMPLE 7

In this experiment the composition of Example 4 was ingested by a competitor in a 3,120 mile bicycle race known as the 1986 Race Across America. During the race one of the bicyclists ingested an amount of said composition containing 45,730 kcal, which comprised 77.3% of that racer's total caloric intake, immediately prior to and following the race, total weight, percent of body fat, and percent lean body mass were determined for this bicyclist (identified by the letter A in Tables 4, 5, and 6, reproduced infra) and for the 6 other competitors completing the race who did not use the compound of the present invention (identified by the letters B, C, D, E, F, and G in the Tables reproduced infra). Percent body fat was computed based upon the electrical resistance measured between a point on a wrist and a point on the opposite ankle using an RJL System BIA-103 body composition analyzer. Lean body mass was the difference between total weight and the amount of body fat.

The raw data are summarized in Tables 4 and 5.

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TABLE 4
PRE-RACE BODY COMPOSITION DATA

10	<u>Contestant</u>	<u>Аде</u>	Ht (in)	Initial Total Weight (1bs)	Initial Skin Resis- tivity (ohms)	Initial % Body Fat	Initial Lean Body Mass (1bs)
	A	· 43	69	140	479	8.3	126.5
15	В	28	73	192	403	9.7	173.4
	С	23	72	168	472	13.1	146.1
	D	26	68	140	507	13.2	121.5
	E	30	73	180	439	11.0	160.2
20	F	29	62	119	571	23.6	90.9
	G	32	68.5	155	588	28.5	110.8

# TABLE 5

POST-RACE	BODY	COMPOSITION	DATA
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						-	
35	<u>Contestant</u>	Final Total Weight (lbs)	Height	Skin Resis- tivity (ohms)	Final %Body Fat	Final Lean Body Mass (lbs)	
40	<b>.</b>	138	69	439	6.9	128.4	
	В	188	73.5	372	7.4	174.1	
	С	160	72	431	7.6	147.9	
45	· . <b>D</b>	133.5	68	397	5.5	126.2	
70	E	175	73	365	6.1	164.4	
	F	110	62	469	. 11.2	97.7	
50	G	160	68	495	22	124.8	

These data have been summarized in the following Table 6 with the competitors arranged in order of finishing time. Competitors A through E were male end F and G were female. This Table Illustrates that competitor A, who used the composition of the present invention, experienced the smallest change in percent body fat, the smallest change in percent total weight, and the second smallest change in lean body mass. That competitor also won the race by more than 22 hours. This experiment demonstrates the remarkable ability of the composition according to the invention to maintain a high degree of stability in terms of the measured body composition variables, under conditions of extraordinary physical stress.

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TABLE 6

Race Finish Times v. Changes in Body Composition

				-	
Contestant	Race Time (hr)	% Change in Body Fat	t Change in Total Weight	Change in Lean Body <u>Mass</u>	10
A	201.78	- 1.4	- 1.4	+ 1.9	15
В	224.03	- 2.3	- 2.1	+ .7	
С	224.95	- 5.5	- 4.8	+ 1.8	
D	239.17	- 7.7	- 4.6	+ 4.7	20
E	245.95	- 4.9	- 2.8	+ 4.2	
F	242.07	-12.4	~ 3.5	+ 6.8	
G	249.48	- 6.5	+ 3.2	+14.0	25

The foregoing data are graphically illustrated in Figure 1. Figure 1 is another example of the utility of this invention. The composition of this invention as shown in Example 4, represented 77.3% of the total caloric intake by contestant A during the 1986 RAAM.

Figure 1 shows pre-race and post-race body composition data for all race finishers. Pre-race are plotted with an symbol and post-rate with an "o" symbol. Lines are drawn between the pre-race and post-race points for each race finisher. Thus, the total length of the line for each race finisher represents the combined change in percent body fat and lean body mass (lbs.).

It can be easily seen that contestant A demonstrated the smallest combined change in these two parameters, or expressed differently, contestant A demonstrated the most stable overall body composition before, during, and after the race.

Although this invention has been described in terms of certain preferred compositions within a stated range, and certain discrete method steps, other embodiments that are apparent to those of ordinary skill in the art are also within the scope of this invention. Accordingly, the scope of the invention is intended to be determined by reference to the appended claims.

### Claims

1. A palatable, orally ingestible nutrient blend, comprising:

free essential and non-essential amino acids, nutrient factors, carbohydrates, electrolytes, and flavoring aids;

wherein the blend is water soluble in 6 minutes or less with simple stirring or shaking and provides substantially all of the nutritional, carbohydrate, and energy requirements of an athlete under conditions of physical stress, without interfering with fluid absorption or causing gastrointestinal disturbances.

- 2. A nutrient blend as claimed in Claim 1, wherein the total free amino acid content comprises at least 20% by weight but not more than 45% by weight branched-chain amino acids.
- 3. A nutrient blend as claimed in Claim 2, wherein the free non-essential amino acids comprise one or more of: L-Alanine, L-Arginine, L-Aspartic acid, L-Glutamic acid, aminoacetic acid, L-Histidine, L-Proline, L-Serlne, LTyrosine, and L-Cysteine.
- 4. A nutrient blend as claimed in any of Claims 1-3, wherein the weight percent of each of the free essential amino acids, expressed as a fraction of total free amino acids, is:

L-Isoleucine 3.00%-25.00% L-Leucine 2.20%-20.00% L-Valine 4.00%-16.00% L-Lysine 1.00%-14.00% L-Methionine 1.00%-11.00%

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L-Phenylalanine 0.0096-5.00% L-Threonine 1.40%-4.40% L-Tryptophan 0.009/6-4.509/6 5. A nutrient blend as claimed in any of Claims 1-4, wherein the weight percent of each of the free nonessential amino acids, expressed as a fraction of total free amino acids, is: 5 L-Alanine 2.00%-15.00% 2.10%-2.40% L-Arginine L-Aspartic Acid 0.30%-6.10% 0.00%-20.40% L-Glutamic Acid Aminoacetic Acid 1,70%-12.30% 10 2.10%-5.00% L-Histidine 3,00%-10.30% L-Profine 2.00%-5.30% L-Serine 0.00%-4.30% L-Tyrosine L-Cysteine 0.0096-1.50%. 15 6. A nutrient blend as claimed in Claim or 2, wherein the weight percent of each of the essential and non-essential free amino acids is: 6.00%-18.00% L-Isoleucine 7.00%-19.00% L-Leucine 10.009/0-14.009/0 L-Valine 20 10.00%-14.00% L-Lysine L-Methionine 1.00%-5.00% 0.009/6-3.009/6 L-Phenylalanine 2.00%-4.00% L-Threonine 25 L-Tryptophan 0.00%-4.00% L-Alanine 7.00%-11.00% L-Arginine 6.00%-10.00% L-Aspartic Acid 0,30%-3.00% 0.00%-6.50% L-Glutamic Acid Aminoacetic Acid 4,009/6-6.009/6 2.10%-4.00% L-Histidine 7.00%-10.00% L-Proline L-Serine 2.00%-3.00% L-Tyrosine 0.00%-1.20% 35 L-Cystine 0.009/0-0.709/0 7. A nutrient blend according to any of Claims 1-5, wherein the nutrient factors comprise one or more of vitamin A, vitamin D3, vitamin E, vitamin C, folic acid, thiamine, riboflavin, niacin, vitamin B8, vitamin B12, biotin, pantothenic acid, vitamin K1, chlorine, calcium, phosphorus, iodine, iron, magnesium, copper, zinc, manganese, selenium, molybdenum, chromium; wherein the electrolytes comprise one or more of 40 sodium chloride, potassium chloride, potassium acetate sodium phosphate, and calcium gluconate; and wherein the carbohydrates comprise one or more of sucrose, glucose, dextrose, fructose, polyglucose, malto-dextrin, and corn syrup. 8. A nutrient blend as claimed in Claim 7, wherein the nutrient factors in a portion thereof containing 16 g free amino acid, are present in an amount of: 45 Vitamin A 1,000-7,500 IU Vitamin D3 150-600 IU Vitamin E 10-45 IU 90-400 mg Vitamin C Folic acid  $0.5-2 \, \text{mg}$ 50 Thiamine 2.3-6 mg Riboflavin 2.6-8 mg Niacin 15-60 mg Vitamin B6 1.5-6. mg 55 Vitamin B12 3-50 mca 0.25-1.8 mg 7.5-90 mg Pantothenic acid Vitamin K1 5-60 mcg 50-300 mg Chlorine 0.4-4 g 60 Calcium Phosphorus 0.25-2 g lodine 50-325 mcg

iron 3-325 mg Magnesium 10

Copper 0.75-6 mg

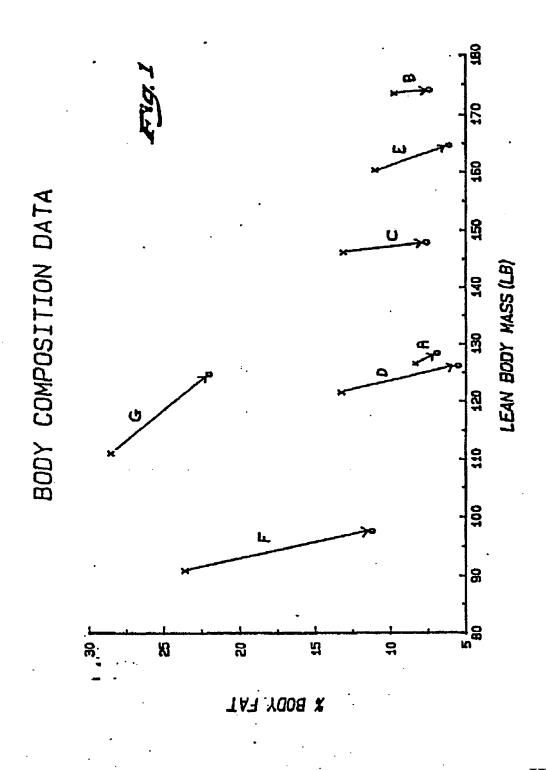
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100-600 mg

Zinc 9-220 mg	
Manganese 0.6-4 mg	
Selenium 20-150 mcg	
Molybdenum 20-150 mcg	
Chromium 10-100 mcg.	5
9. A nutrient blend as claimed in Claim 7 or 8, wherein the electrolytes, in a portion of said blend which	
contains 16 g free amino acids, are present in amounts of;	
Sodium Chloride 20-150 mEg	
Potassium Chloride 1-80 mEa	
Potassium Acetate 5-60 mEg	10
Sodium Phosphate 1-30 mMol	,,
Calcium Gluconate 0.46-20 mEq.	
10. A nutrient blend as claimed in any of Claims 7-9, wherein the carbohydrates, in a portion of said blend	
which contains 16 g free amino acids, are present in amounts of:	
Sucrose 20-100 grams	15
Glucose 10-40 grams	15
Dextrose 10-60 grams	
Fructose 10-40 grams	
Poly-Glucose 60-180 grams	
Malto-Dextrin 90-250 grams	20
Com Syrup 50-120 grams.	
11. A nutrient blend as claimed in any of Claims 7-10, wherein the flavoring aids, in a portion of said blend	
which contains 16 g free amino acids, are present in amounts of:	
Cocoa 20-85 grams	
Carob Powder 20-125 grams	25
Vanilla Extract 0.25-2 grams	
Powdered Non-Fat Milk 0-400 grams.	
12. A nutrient composition as claimed in any of Claims 1-11, wherein the amino acids, expressed as a	
weight percent of 16 g total free amino acids, comprise:	
L-isoleucine 15.50% ±2%	30
L-Leucine 16.00% ± 2%	
L-Valine 10.69% ±2%	
L-Lysine 13.92 ± 2%	
L-Methionine 2.10% ± 1%	
L-Phenylalanine 0.41% ±0.2%	35
L-Threonine 2.90% ± 1.5%	•
L-Tryptophan 1.02% ± 0.5%	
L-Alanine 9.30% ± 2%	
L-Arginine 8.22%±2%	
L-Aspartic Acid 0.32% ± 0.15%	40
Aminoacetic Acid 3.91% ± 1.8%	70
L-Histidine 4.02% ±2%	
L-Proline 8.38% ±2%	
L-Serine 2.39% ± 1%	
L-Tyrosine 0.47% ±0.2%	45
L-Cysteine 0.45% ±0.2%	40
wherein the nutrient factors are present in the amounts of:	
Vitamin A 1.500.00 IU	
Vitamin E 9.00 IU	50
Vitamin C 36.00 mg	
Folic acid 0.24 mg	
Thiamine 0.90 mg	
Riboflavin 1.20 mg	
Nlacin 12.00 mg	55
Vitamin B6 1.20 mg	
Vitamin B12 3.60 mcg	
Biotin 3.00 mg	
Pantothenic acid 6.00 mg	
Vitamin K1 13.40 mcg	60
Chlorine 44.20 mcg	
Calcium 300.00 mg	
Phosphorous 300.00 mg	
lodine 45.00 mcg	
Magnasium 100 00 —	

0.60 mg Copper Zino 6.00 mg 562.00 mcg Manganese Selenium 30.00 mcg Molybdenum 30.00 mcg 5 10.00 mcg Chromium Iron 4.80 mg; the electrolytes are present in amounts of: Sodium Chloride 20.50 mEq 10 Potassium Chloride 6.70 mEq Calcium Gluconate 6.97 mEq Sodium Phosphate 7.24 mMol 1000 mg; Ascorbic Acid the carbohydrates are present in amounts of: 15 Sucrose 25 grams Fructose 5 grams Dextrose 59 grams Malto-Dextrin 211 grams; and the flavoring aids are present in amounts of: Cocoa 50 grams 20 Non-Fat Dry Milk 90 grams. 13. A method for the preparation of a water-soluble, palatable, orally ingastible nutrient bland, (a) dry blending a first mixture comprising substantially pure free essential and non-essential amino acids until a transition from discrete crystals to a fine, amorphous powder appearance is 25 achieved; and thereafter (b) blending said first mixture with additives comprising one or more of vitamins, trace elements. minerals, simple and complex carbohydrates, electrolytes, and flavoring aids, until a uniform consistency is achieved. 14. A method for the preparation of a water soluble nutrient blend, comprising the steps of: 30 (a) blending a first mixture of free amino acids under conditions that cause a transformation from discrete crystals to a fine amorphous powder; (b) blending a second mixture of nutrient factors under conditions that yield a uniform particle size of 10 to 20 microns; and (c) blending the first and second mixtures together with at least one additive selected from the 35 group consisting of carbohydrates, electrolytes and flavoring alds, until a homogeneous powder is achieved. 15. A method of meeting the nutritional requirements of an athlete, said method comprising: orally administering to an athlete undergoing physical stress a composition according to any of Claims 1-12, thereby providing substantially all of the nutritional, carbohydrate and energy requirements of said 40 athlete under conditions of physical stress without interfering with fluid absorption or causing gastrointestinal disturbances. 45 50

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